UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,164	01/19/2006	Sung-Kee Chung	Q92717	5253

23373 7590 12/11/2007

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER
KELLY, ROBERT M

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
12/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,164	CHUNG ET AL.	
	Examiner	Art Unit	
	Robert M. Kelly	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☒ Claim(s) *6 and 7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 January 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Telephonic Interview

On the 20th of November, 2007, the Examiner was contacted by Ms. Li, attorney for Applicant, to discuss the restriction requirement of 10/16/07. Ms. Li informed the Examiner that the Restriction requirement was drawn to inventions which were not related to the presently filed claims. The Examiner reviewed the restriction requirement and determined that, due to typographical error, the restriction requirement was incorrectly sent to Applicant. In light of this, the Examiner agreed to issue a new action or new restriction requirement and withdraw the restriction requirement.

Hence, the Restriction requirement of 10/16/07 is withdrawn in favor of the following Official Action.

Claims 1-13 are presently pending and considered.

Information Disclosure Statement

Applicant's IDS of 1/19/06 has been considered. However, the WIPO document and the Rothbard reference were not supplied. On the other hand, the Examiner was able to obtain such documents, and hence, while considered, the references have been crossed out and also supplied with the PTO-892 which is attached, for purposes of compact prosecution.

ABSTRACT

It is noted that Applicant has supplied a copy of the PCT front page for the abstract. While such is acceptable, it is recommended that Applicant provide a separate amended sheet with the abstract, as such is required for office procedures, and would avoid the Examiner having to obtain permission to provide a new copy of the abstract by way of Examiner's amendment prior to allowance.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the Examiner cannot differentiate the particulars of the drawings. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

It is noted that the drawings appear to be black-and-white line drawings (photocopies) of pictures. It is recommended that Applicant provide the actual pictures, along with any required petitions to accept color drawings or an explanation that no other form of drawing is possible but the pictures (if black and white), thereby complying with Office procedures.

Claim Objections

Claim 7 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from two claims in any form other than an

alternative form. Claim 7 depends from Claim 1 and Claim 6, requiring limitations from each. See MPEP § 608.01(n). Accordingly, Claim 7 has not been further treated on the merits.

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 6 does not limit l, m, and n, to levels commensurate with that in claim 1, while subsequent dependent claim 7 does, indicating that l, m, and n, are broader than the claim from which Claim 6 depends (Claim 1).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 6 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after

allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 6, which is drawn to the composition with an intended use, does not alter the structure of the composition such that it is patentably distinct. Moreover, intended use does not alter a finding of double-patenting. It would be remedial to amend the claim to include the drug or diagnostic agent in the composition.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected for recitation of "obtaining inositol polymers by coupling two or more of the intermediates obtained in step (a)." Specifically, if these polymers are coupled by any method, they would contain the proper X and X' groups. It would be remedial to fix the coupling method to make clear that the coupling is carried out to yield the various X and X' couplings.

Claim 6 is rejected for the recitation of "introducing one or more amino acids to the inositol polymer obtained in step (b) by acylation". Specifically, if the amino acids are not required to be commensurate with the obtained product of OR1, it is unclear how the subsequent guanidinum groups will yield a compound of the required structure. It would be remedial to make the amino acids commensurate in scope.

Claim 6 is rejected for the recitation of "introducing guanidium groups to the amino acid N-terminal of the inositol polymer". It is unclear how the inositol polymer could have an N-terminus, as such is terminology used for polypeptides, not polyinositols. It would be remedial to recite that the OR1 groups are guanidated at the NH2 groups.

Claim 7 is rejected for depending from a rejected base claim.

Claims 9-12 are rejected for recitations of characteristics of drugs and/or diagnostic reagents, without further requiring the drug and/or diagnostic reagent to be present in the composition. Hence, the Artisan would not know if the drug or diagnostic reagent would be required to infringe the claim.

Claim 13 provides for the use of an inositol derivative, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 13 is also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for delivering a drug or diagnostic agent across a cellular membrane into a cell, does not reasonably provide enablement for transport across the nuclear membrane into a nucleus. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The enablement rejection is predicted on the fact that the poly-guanidinum transfection reagents do not cause transduction of the nuclear membrane, but only the cell membrane, increasing the probability of the reagent/drug entering the nucleus. The compounds are also rejected as such is the only purpose provided for the compounds claimed, and hence, given that the only method claim (Claim 13) and only intended use provided (Claim 8) encompass the specific translocation into a nucleus, it is clear that all the claims are drawn to such intended use.

At the time of invention, it was known that polyguanidinum compounds only specifically caused increased translocation across the cell membrane (e.g., Lundberg, et al. (2003) Molecular Therapy, 8(1): 143-50, ABSTRACT).

Applicant provides no evidence to overcome such showing and the specification in general only describes the intended use broadly. Hence, there exists no specific guidance or examples to overcome what was known in the Art.

Hence, the Artisan would have to experiment to determine if nuclei could be specifically transformed with the compositions specifically for every type of cell nucleus, which is undue experimentation as it is required to determine if the specifically claimed embodiments would work for the majority of such specifically claimed embodiments.

Therefore, the claims are only enabled for that scope given in the initial form paragraphs.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Kelly, Ph.D.
Examiner, USPTO, AU 1633
Patents Hoteling Program
Mailbox 2C70, Remsen Building
(571) 272-0729